UNITED STATES ENVIRONMENTAL PROTECTION AGENCY REGION IX 75 HAWTHORNE STREET SAN FRANCISCO, CA 94105

In the matter of:)	ORDER
)	SECTION 13(a)
)	
O.C.C.S. Inc.)	FEDERAL INSECTICIDE, FUNGICIDE
)	AND RODENTICIDE ACT
)	
	Respondent.)	Docket No. FIFRA- 09-2020-450
)	

I. AUTHORITIES

- 1. The United States Environmental Protection Agency ("EPA") is authorized under Section 13(a) of the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136k(a), to issue an order prohibiting the sale, use, or removal of any pesticide or device by any person who owns, controls, or has custody of such pesticide or device whenever there is a reason to believe that, *inter alia*, the pesticide or device is in violation of any provision of FIFRA, or the pesticide or device has been or is intended to be distributed or sold in violation of any provision of FIFRA.
- 2. This authority has been delegated from the EPA Administrator to the Manager of the Toxics Branch, Enforcement & Compliance Assurance Division, EPA, Region IX.
- 3. Section 2(s) of FIFRA, 7 U.S.C. § 136(s), defines a "person" as "any individual, partnership, association, corporation, or any organized group of persons whether incorporated or not."
- 4. Section 2(t) of FIFRA, 7 U.S.C. § 136(t), defines "pest," in part, as any "form of terrestrial or aquatic plant or animal life or virus, bacteria, or other micro-organism (except viruses, bacteria, or other micro-organisms on or in living man or other living animals) which the Administrator declares to be a pest under section 25(c)(1)." Pursuant to the authority in section 25(c)(1) of FIFRA, 7 U.S.C. § 136w(c)(1), the Administrator declared that a pest is "[a]ny fungus, bacterium, virus, prion, or other microorganism, except for those on or in living man or other living animals and those on or in processed food or processed animal feed, beverages, drugs . . . and cosmetics. . . ." 40 C.F.R. § 152.5.
- 5. Section 2(gg) of FIFRA, 7 U.S.C. § 136(gg), defines "distribute or sell" as "to distribute, sell, offer for sale, hold for distribution, hold for sale, hold for shipment, ship, deliver for

shipment, release for shipment, or receive and (having so received) deliver or offer to deliver."

- 6. Section 2(u) of FIFRA, 7 U.S.C. § 136(u), defines a "pesticide" in part, as any "substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest." See also 40 C.F.R. § 152.15. 40 C.F.R. § 152.15 states in pertinent part that "a pesticide is any substance (or mixture of substances) intended for a pesticidal purpose..." and that a substance is considered to be intended for a pesticidal purpose, and thus to be a pesticide requiring registration, if: (a) The person who distributes or sells the substance claims, states, or implies (by labeling or otherwise): (1) That the substance (either by itself or in combination with any other substance) can or should be used as a pesticide; or (2) That the substance consists of or contains an active ingredient and that it can be used to manufacture a pesticide; or (b) The substance consists of or contains one or more active ingredients and has no significant commercially valuable use as distributed or sold other than (1) use for pesticidal purpose (by itself or in combination with any other substance), (2) use for manufacture of a pesticide; or (c) The person who distributes or sells the substance has actual or constructive knowledge that the substance will be used, or is intended to be used, for a pesticidal purpose.
- 7. Section 2(p) of FIFRA, 7 U.S.C. § 136(p), defines "labeling" in part, as "all labels and all other written, printed, or graphic matter
 - (A) accompanying the pesticide or device at any time; or
 - (B) to which reference is made on the label or in literature accompanying the pesticide..." and defines "label" as "the written, printed, or graphic matter on, or attached to, the pesticide or device or any of its containers or wrappers."
- 8. Section 2(q)(1) of FIFRA, 7 U.S.C. § 136(q), states that "a pesticide is misbranded if (A) its labeling bears any statement, design, or graphic representation relative thereto or to its ingredients which is false or misleading in any particular;
 - (E) Any word, statement, or other information required by or under the authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared to other words, statements, designs, or graphic matter in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use; ..."
- 9. Section 3(a) of FIFRA, 7 U.S.C. § 136a, provides that "no person in any State may distribute or sell to any person any pesticide that is not registered under this Act." See also 40 C.F.R. 152.15, which also provides that no person may distribute or sell any pesticide that is not registered under the Act, with certain exceptions not applicable here.
- 10. Section 3(c)(1)(C) of FIFRA, 7 U.S.C. § 136a, provides that the statement that each applicant for registration of a pesticide must file a statement includes "a complete copy of the labeling of the pesticide, a statement of all claims to be made for it, and any directions for its use."

- 11. 40 C.F.R. § 152.132 provides for "supplemental distribution" the term for when the registrant may distribute or sell his registered product under another person's name and address, and such distributor is considered an agent of the registrant for all intents and purposes under the Act. Supplemental distribution is permitted upon notification to EPA if all the following conditions are met:
 - (a) The registrant has submitted to the Agency for each distributor product a statement signed by both the registrant and the distributor listing the names and addresses of the registrant and the distributor, the distributor's company number, the additional brand name(s) to be used, and the registration number of the registered product. (40 C.F.R. § 152.132(a))
 - (b) The distributor product is produced, packaged and labeled in a registered establishment operated by the same producer (or under contract in accordance with §152.30) who produces, packages, and labels the registered product. (40 C.F.R. § 152.132(b))
 - (c) The distributor product is not repackaged (remains in the producer's unopened container). (40 C.F.R. § 152.132(c))
 - (d) The label of the distributor product is the same as that of the registered product, except that: (1) The product name of the distributor product may be different (but may not be misleading); (2) The name and address of the distributor may appear instead of that of the registrant; (3) The registration number of the registered product must be followed by a dash, followed by the distributor's company number (obtainable from the Agency upon request); (4) The establishment number must be that of the final establishment at which the product was produced; and (5) Specific claims may be deleted, provided that no other changes are necessary. (40 C.F.R. § 152.132(d))
 - (e) Voluntary cancellation of a product applies to the registered product and all distributor products distributed or sold under that registration number. The registrant is responsible for ensuring that distributors under his cancelled registration are notified and comply with the terms of the cancellation. (40 C.F.R. § 152.132(e)).
- 12. Section 12(a)(1)(B) of FIFRA, 7 U.S.C. § 136j(a)(1)(B), states, "it shall be unlawful for any person in any State to distribute or sell to any person . . . any registered pesticide if any claims made for it as part of its distribution or sale substantially differ from any claims made for it as a part of the statement required in connection with its registration" under section 3 of FIFRA.
- 13. Section 12(a)(1)(A) of FIFRA, 7 U.S.C. § 136j(a)(1)(A), states, "it shall be unlawful for any person in any State to distribute or sell to any person . . . any pesticide that is not registered . . . or whose registration has been suspended or cancelled."

- 14. Section 12(a)(1)(E) of FIFRA, 7 U.S.C. § 136j(a)(1)(E), states, "it shall be unlawful for any person in any State to distribute or sell to any person . . . any pesticide which is adulterated or misbranded."
- 15. Section 12(a)(2)(S) of FIFRA, 7 U.S.C. § 136j(a)(2)(S), states, "it shall be unlawful to violate any regulation issued under FIFRA section 3(a) or section 19."
- 16. Section 12(a)(2)(I) of FIFRA, 7 U.S.C. § 136j(a)(2)(1), states that it shall be unlawful for any person to violate any order issued under section 13 of FIFRA.

II. BACKGROUND

- 17. This Order refers to O.C.C.S. Inc. as "OCCS" or the "Respondent."
- 18. OCCS is a corporation organized under the laws of the State of California and is authorized to do business in the State of California. OCCS is a "person" as defined in section 2(s) of FIFRA, 7 U.S.C. § 136(s).
- 19. OCCS is a supplemental distributor for Maquat 10, a pesticide which has been assigned the EPA Registration Number ("EPA Reg. No.") 10324-63 ("Maquat 10"). The registrant of Maquat 10 is the Mason Chemical Company.
- 20. Maquat 10 has 10% active ingredients consisting of 5 percent (5%) of each Alkyl (60% C14, 30% C16, 5% C12, 5% C18) Dimethyl Benzyl Ammonium Chloride and Alkyl (68% C12, 32% C14) Dimethyl Ethylbenzyl Ammonium Chloride. Maquat 10 is sold as a concentrate that must be diluted according to the instructions on the EPA-approved label to be used to kill the bacteria including Staphylococcus aureus, viruses including the Human Coronavirus, and fungi including Trichophyton mentagrophytes listed on the label.
- 21. Bacteria including Staphylococcus aureus, viruses including the Human Coronavirus, and fungi including Trichophyton mentagrophytes are each "pests" within the meaning of section 2(t) of FIFRA, 7 U.S.C. § 136(t).
- 22. OCCS is a supplemental distributor of Maquat 10 under distributor product names that include "SANITIZER/QUAT SOLUTION CONCENTRATE-10%" with the EPA Reg. No. 10324-63-74439 ("SANITIZER/QUAT SOLUTION CONCENTRATE-10%").

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¹ It is a common practice for a registered product to have alternate brand names. In accordance with 40 CFR § 152.46 and Pesticide Registration (PR) Notice 98-10, alternate brand names are submitted to the EPA for approval using the notification procedures outlined in that PR Notice.

III. BASIS FOR ORDER

- 23. On or about March 30, 2020, EPA Region 9 received information regarding potential FIFRA violations associated with OCCS's distribution and sale of Sanitizer / Quat Solution Ready to Use DISINFECTANT SANITIZER ("S/Q Ready to Use"), including a copy of the label.
- 24. On or about May 29, 2020, a "for cause" inspection pursuant to court-issued warrant was conducted at OCCS located at 10680 Fern Ave., Stanton CA 90680 by EPA special agents. A Region 9 FIFRA civil inspector participated in the inspection by telephone (due to coronavirus shelter-in-place policies).
- 25. Review of the information collected during the inspection revealed the following observations, as referenced in Paragraphs **26** through **37**, below.
- 26. Review of the **S/Q Ready to Use** label resulted in the following observations:
 - A. The label for **S/Q Ready to Use** identifies that the product has one percent active ingredients because it states that the active ingredients consist of .5% of each of the following active ingredients:
 - i. Alkyl (60% C14, 30% C16, 5% C12, 5% C18) Dimethyl Benzyl Ammonium Chloride; and
 - ii. Alkyl (68% C12, 32% C14) Dimethyl Ethylbenzyl Ammonium Chloride.
 - B. The label for **S/Q Ready to Use** states the product kills bacteria including Staphylococcus aureus, viruses including the Human Coronavirus, and the fungi Trichophyton mentagrophytes on hard, non-porous surfaces.
 - C. The label for S/Q Ready to Use product identifies it as "Item 3166".
- 27. Additionally, the inspection documented that product originally labeled with the **S/Q Ready to Use** label described above in Paragraph <u>26</u> had a new label affixed on it. This new label identifies that product as "Quat Solution Ready to Use Cleaner" ("Quat Ready to Use").
- 28. Review of the **Quat Ready to Use** label resulted in the following observations:
 - A. The label for **Quat Ready to Use** identifies that the product has .08 percent active ingredients because it states that the active ingredients consist of .04% of each of the following active ingredients:
 - i. Alkyl (60% C14, 30% C16, 5% C12, 5% C18) Dimethyl Benzyl Ammonium Chloride; and
 - ii. Alkyl (68% C12, 32% C14) Dimethyl Ethylbenzyl Ammonium Chloride.

- B. The label for **Quat Ready to Use** states "It contains a Quatenary ammonium, MAQUAT 10 EPA Reg. No 10324-63, which is the main cleaning agent used in this product. For more information on this chemical, please see the manufactures website. For use as a cleaner in food plants, food establishments, food areas, equipment, homes, hospitals, nursing homes, health care institutions, schools, food services, and farms."
- C. The label for **Quat Ready to Use** product identifies it as "Item 3166".
- D. The label for **Quat Ready to Use** states "Disposal: Pesticide wastes are acutely hazardous..."

Pesticide

- 29. The **S/Q Ready to Use** product is a "pesticide" within the meaning of section 2(u) of FIFRA, 7 U.S.C. § 136(u).
- 30. Evidence that the **S/Q Ready to Use** product is a pesticide includes that it identifies itself as a pesticide, is labeled as a pesticide, and has active ingredients for pesticidal use.
- 31. The **Quat Ready to Use product is** a "pesticide" within the meaning of section 2(u) of FIFRA, 7 U.S.C. § 136(u).
- 32. Evidence that the **Quat Ready to Use** product is a substance intended for a pesticidal purpose and thus a pesticide requiring registration pursuant to 40 C.F.R. § 152.15 includes:
 - A. Use of the same item number, 3166, on both the **S/Q Ready to Use** product and the **Quat Ready to Use** product;
 - B. Incorporation of a registered pesticide into the product;
 - C. Statements on the **Quat Ready to Use** label that an EPA registered pesticide is the main "cleaning agent" used in the product;
 - D. Statements on the **Quat Ready to Use** label that that the "MAQUAT 10 EPA Reg. No 10324-63 manufacturer's website should be consulted for more information"; and
 - E. Inclusion of the term "pesticide wastes" when giving disposal instructions.

Unregistered Pesticide

33. The pesticide **S/Q Ready to Use** is identified on its label as a supplemental distributor pesticide product ("distributor product") of Maquat 10 by including on the product label the EPA Registration Number 10324-63-74439.

- 34. EPA has reason to believe that production of the **S/Q Ready to Use** product does not meet the requirements for supplemental distribution at 40 C.F.R. § 152.132.
 - A. One of these requirements is that the product name of the distributor product may not be misleading. 40 C.F.R. § 152.132(d)(1). Here the use of the term "ready to use" in the product name is misleading for a distributor product of Maquat 10 because Maquat 10 is sold as a concentrate that must be diluted according to the instructions on the EPA-approved label.
 - B. Another requirement is that the distributor product may not be repackaged. 40 C.F.R. § 152.132(c). But the label of **S/Q Ready to Use** states that it contains 0.5% of each of its active ingredients in contrast to Maquat 10, which states that it contains 5% of each of its active ingredients.
- 35. The product **S/Q Ready to Use** does not meet the requirements for supplemental distribution and therefore it is not a registered pesticide.
- 36. The product **Quat Ready to Use** is not a registered pesticide.
- 37. EPA has reason to believe that each of the **S/Q Ready to Use** and the **Quat Ready to Use** products is an unregistered pesticide product whose distribution and sale is prohibited under section 12(a)(1)(A) of FIFRA, 7 U.S.C. § 136j(a)(1)(A).

Summary of Basis for the Order

38. Since EPA has determined that each of the **S/Q Ready to Use** and the **Quat Ready to Use** products is a pesticide that is not registered under Section 3 of FIFRA, 7 U.S.C. § 136a, and EPA has reason to believe that Respondent has distributed and sold these products, EPA has reason to believe that Respondent distributed or sold unregistered pesticides in violation of section 12(a)(1)(A) of FIFRA, 7 U.S.C. § 136j(a)(1)(A).

III. ORDER

- 39. Pursuant to the authority in section 13(a) of FIFRA, 7 U.S.C. § 136k(a), EPA hereby orders Respondent to **immediately stop** the sale, use or removal of the **S/Q Ready to Use** and the **Quat Ready to Use** products under its ownership, control, or custody, wherever such products are located, except in accordance with the provisions of this Order.
- 40. This Order shall extend to all quantities and sizes of the **S/Q Ready to Use** and the **Quat Ready to Use** products intended for sale or distribution, including:
 - A. Any **S/Q Ready to Use** and **Quat Ready to Use** products marketed under alternate brand names; and
 - B. Any **S/Q Ready to Use** and **Quat Ready to Use** products returned to Respondent from its distributors, customers, or other end-users.

- 41. The products described in Paragraph <u>39</u> shall not be used, sold, offered for sale, held for sale, shipped, delivered for shipment, received, or having so received, shall not be delivered, offered for delivery, moved or removed for disposal from any facility or establishment for any reason, unless approved by EPA in writing. Any proposal for movement of the products so described shall be submitted by email to Scott McWhorter, Enforcement and Compliance Assurance Division, U.S. Environmental Protection Agency, Region IX, at mcwhorter.scott@epa.gov, and shall include:
 - A. The purpose for which the movement is being requested;
 - B. An accounting of the quantities of the product to be moved, including location(s), quantities from each location, and container size for the products to be moved; and
 - C. The destination location to which the product will be moved.
- 42. Within 10 days of receipt of this Order, Respondent shall submit to EPA an accounting of all products subject to this Order. The report shall be submitted by email to Scott McWhorter, Enforcement and Compliance Assurance Division, U.S. Environmental Protection Agency, Region IX, at mcwhorter.scott@epa.gov, and shall include:
 - A. A description of all existing product inventory, including the location(s) where the products are held, quantities, and container size. This information must be updated on a weekly basis for four weeks, on a monthly basis for the following six months, and thereafter only upon further change to the information;
 - B. A complete list of Respondent's distributors and direct-sale customers and records of all sales and distributions made to such entities since January 1, 2020; and
 - C. Provisions to maintain records of the distribution (e.g., reformulation, repackaging, relabeling, disposal) of products and to make the records available to EPA upon request. Such records must include information on the method, the quantity, and the location of the disposition and/or disposal.
 - D. You may, if you desire, assert a business confidentiality claim for all or part of the information submitted in accordance with 40 C.F.R. Part 2. The information qualifying as business confidential material will be disclosed by EPA only to the extent and by the procedures set forth in 40 C.F.R. Part 2 Subpart B. Unless you make a claim at the time you submit the information, it may be made available to the public by EPA without further notice to you. If you do assert a business confidentiality claim, you must follow the procedures set forth in the attached Exhibit A. All submittals that are claimed confidential business information shall be submitted with password protection, via email to Scott McWhorter at mcwhorter.scott@epa.gov.

- 43. Any agent, owner, or operator of OCCS violating the terms or provisions of this Order may subject the violator to civil or criminal penalties as prescribed in section 14 of FIFRA, 7 U.S.C. § 136*l*.
- 44. The issuance of this Order shall not constitute a waiver by EPA of its remedies, either judicial or administrative, under FIFRA or any other federal environmental law to address this matter or any other matters or unlawful acts not specified in this Order.
- 45. This Order shall be effective immediately upon receipt by OCCS, or any agents of OCCS.
- 46. This Order shall remain in effect unless and until revoked, terminated, suspended, or modified in writing by EPA.
- 47. If any provision or provisions of this Order is/are subsequently held to be invalid, illegal, or unenforceable, the validity, legality, and enforceability of the remaining provisions shall not in any way be affected or impaired thereby and they shall remain in full force and effect.

V. OTHER MATTERS

- 48. Respondent may seek federal judicial review of this Order pursuant to Section 16 of FIFRA, 7 U.S.C. § 136n.
- 49. For additional information about this Order, please contact Scott McWhorter, Enforcement Case Officer, at 415-972-3584. For any legal matters concerning this matter, please contact Margaret Alkon, Attorney, at 415-972-3890.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, COMPLAINANT

DATE: June 12, 2020 By:

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Matt Salazar Manager, Toxics Branch Enforcement & Compliance Assurance Division U.S. Environmental Protection Agency, Region IX

EXHIBIT A

If you wish to assert a claim of business confidentiality, you must clearly mark each page of each document included in your claim with a legend such as "trade secret", "proprietary", or "company confidential." If you claim information submitted as confidential, you must also provide a redacted version of the information with all confidential business information deleted. For any information and documents in which you assert a claim of business confidentiality, please answer the following questions:

- 1. What specific portions of the information are alleged to be entitled to confidential treatment? Specify by page, paragraph, and sentence when identifying the information subject to your claim.
- 2. For what period of time do you request that the information be maintained as confidential (*e.g.*, until a certain date, until the occurrence of a specified event or permanently)? If the occurrence of a specific event will eliminate the need for confidentiality, specify that event. Additionally, explain why the information should be protected for the time period you have specified.
- 3. What measures have you taken to protect the information claimed as confidential from undesired disclosure? Have you disclosed the information to anyone other than a governmental body or someone who is bound by an agreement not to disclose the information further? If so, why should the information still be considered confidential?
- 4. Is the information contained in any publicly available material such as the Internet, publicly available databases, promotional publications, annual reports or articles? Is there any means by which a member of the public could obtain access to the information? Is the information of a kind that you would customarily not release to the public?
- 5. Has any governmental body made a determination as to the confidentiality of the information? If so, please attach a copy of the determination.
- 6. For each category of information claimed as confidential, explain with specificity whether disclosure of the information is likely to result in substantial harm to your competitive position. Explain the specific nature of those harmful effects, why they should be viewed as substantial, and the causal relationship between disclosure and such harmful effect. How could your competitors make use of this information to your detriment?
- 7. Is there any other explanation you deem relevant to the EPA's determination of your business confidentiality claim that is not covered in the preceding requests? If so, you may provide such additional explanation.

You must furnish comments to the above requests concurrent with your response, if you have claimed any information as business confidential. See 40 C.F.R. § 2.204(e)(2). Pursuant to 40 C.F.R. § 2.205(b)(2), you may request an extension of this deadline. The EPA will construe your failure to furnish timely comments as a waiver of your confidentiality claim, consistent with 40 C.F.R. § 2.204(e)(1).